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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/878,574

06/11/2001

Francis Sullivan

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4282

7590

03/26/2003

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,574

Applicant(s)

SULLIVAN ET AL.

Examiner

Yong Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) 9,22,24,25 and 30-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,23 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a continuation of 09/333,177, which is a divisional of 09/149,674, which is a divisional of 08/984,246, which is a divisional of 08/753,233.

Claims 9 and 21-37 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, claims 21 and 26-29 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Groups II, IV, VI and VII are classified in class 424, subclass 130.1 and therefore no serious burden exists. Group VI has been joined with Group II and Group VIII (this group was incorrectly labeled as Group VI) has been joined with Group IV. However, Group II and IV remain patentably distinct because the two groups are drawn to treating different disorders. A defect in fucosylation does not necessarily included defect in GM4,6D activity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9, 22, 24-25 and 30-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claim Objections

Claims 26-29 are objected for being drawn to non-elected claim 22.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a process of using modulators of a GDP-mannose-4,6-dehydratase (GM4,6D). Therefore, these claims are drawn to a genus of GM4,6D, with any structure and source and a genus of modulators, with any structure. In order to treat a subject having aberrant GM4,6D activity with modulators, the enzyme must first be known. The specification only teaches two GM4,6D, SEQ ID NO:2 and 3. These two representative species is not enough to describe the whole genus and there is no evidence on the record of the relationship between the structure of SEQ ID NO:2 and 3 and the structure of a GM4,6D from another source. Therefore, the specification fails to describe other representative species of the genus of GM4,6D.

Further, the requirement for written description cannot be satisfied by merely providing the desired function of the modulator without more detail on the modulator's structure, chemical formula, chemical name, or physical properties. The specification

Art Unit: 1652

only teaches treating a subject with aberrant GM4,6D (SEQ ID NO:2 and 3) activity with antibodies against the GM4,6D of SEQ ID NO:2 and 3.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claim 21, 23 and 26-29.

Claims 21, 23 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a subject with antibodies against the GM4,6D of SEQ ID NO:2 and 3, does not reasonably provide enablement for treating a subject with any modulators against GM4,6D or antibodies against GM4,6D different from SEQ ID NO:2 and 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Art Unit: 1652

In order to practice the claimed invention, the structure of the GM4,6D must be known in order to raise up antibodies or design modulators. However, the specification only teaches GM4,6D of SEQ ID NO:2 and 3. The specification only teaches modulators that are antibodies against the GM4,6D of SEQ ID NO:2 and 2. The specification does not teach modulators or antibodies against GM4,6D different from SEQ ID NO:2 and 3.

Despite knowledge in the art for the isolation of amino acids, the specification fails to provide guidance regarding how to isolate other GM4,6D whose sequence is not homologous to that of SEQ ID NO:2 and 3. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other carbonyl reductase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to treat a subject with modulators against GM4,6D of SEQ ID NO:2 and 3 and antibodies against GM4,6D different from SEQ ID NO:2 and 3 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Art Unit: 1652

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 23 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The mere recitation of the name "GM4,6D" is insufficient to convey with clarity that which applicant sees as the invention.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M. weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

March 20, 2003


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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